510(k) Summary
Multichem P

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k131992

1.0 Submitter:

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SEP 2 5 2013

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2.0 Date Submitted:

August 20, 2013

3.0 Device Identification

Proprietary Names:	Multichem P
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classification:	Class 1, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

4.0 Legally Marketed Predicate Device

Candidate(s)	Predicate	Manufacturer	Document Number
Multichem P	Liquichek™ Immunology Control	Bio-Rad Laboratories	K022991

The Multichem P Control is substantially equivalent to the previously cleared Bio-Rad product listed above, currently in commercial distribution.

5.0 Device Description

The Multichem P control is prepared from human serum to which purified biochemical material (extracts of human origin), chemicals, drugs/preservatives and stabilizers have been added. The control is used in liquid form for convenience. This control is provided in a single level control only with twelve vials, each vial containing 3 mL.

The following kit configurations are available:

Multichem P
(Abbott Distributed)
Model 05P81-10 with Level P control; 12 vials with 3 mL contents
The vial label is SP40PA

Multichem P
(Technopath Distributed)
Model SP41PA with Level P control; 12 vials with 3 mL contents
The vial label is SP41PA

All human source material was tested and found negative by FDA approved methods for HBSAg, HCV and HIV-1/2.

6.0 Intended Use

Multichem P is intended for use as a single level assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

The following analytes are listed in the package insert:
Alpha-1 Acidglycoprotein, Alpha-1 Antitrypsin, Apolipoprotein A1 (APO A1), Apolipoprotein B (APO B), Beta-2 Microglobulin, Ceruloplasmin, Complement C3, Complement C4, C-Reactive Protein, Haptoglobin, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Prealbumin, Rheumatoid Factor (RF), and Transferrin.

7.0 Comparison to the Predicate

Multichem P control claims to be substantially equivalent to Liquichek™ Immunology Control. The controls have same/similar design and modes of operation. The key features are summarized in the following table.

Characteristics	Predicate Device: Liquichek™ Immunology Control: Catalog #596	Candidate Device: Multichem P Control
	Similarities	
Intended Use:	Liquichek Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Multichem P is intended for use as a single level assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert

Characteristics	Predicate Device: Liquichek™ Immunology Control: Catalog #596	Candidate Device: Multichem P Control
Form:	Liquid, Frozen	Liquid, Frozen
Matrix:	Human serum based	Human serum based
Storage: (Closed/Shelf-Life)	-20°C to -70°C until expiration date	-20°C to -80°C until expiration date
	Differences	
(Opened/Shelf-life)	30 days 2 to 8°C, except Beta-2-Microglobulin, 21 days; Rheumatoid Factor, 5 days.	14 days 2 to 8°C
Assayed Analytes	<u>Contains:</u> AdNase B (Antideoxyribonuclease-B) Albumin Alpha 1-Antitrypsin Alpha 2 Macroglobulin Alpha-1-Acid glycoprotein Antistreptolysin-0 Antithrombin III (AT III) Apolipoprotein A-1 Apolipoprotein B Beta-2-Microglobulin C1 Inhibitor Ceruloplasmin Complement C3 Complement C4 C-Reactive Protein (CRP) Cystatin C Ferritin Haptoglobin IgG Subclass 1 IgG Subclass 2 IgG Subclass 3 IgG Subclass 4 Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Kappa Light Chain Lambda Light Chain Lipoprotein (a) Prealbumin Protein, Total Rheumatoid Factor Transferrin	<u>Contains:</u> Alpha-1 Antitrypsin Alpha-1 Acidglycoprotein Apolipoprotein A1 (APO A1) Apolipoprotein B (APO B) Beta-2 Microglobulin Ceruloplasmin Complement C3 Complement C4 C-Reactive Protein Haptoglobin Immunoglobulin A Immunoglobulin G Immunoglobulin M Prealbumin Rheumatoid Factor (RF) Transferrin

8.0 Performance Characteristics

8.1 Value Assignment Summary

Value assignment testing was performed utilizing internal procedures and protocols to determine typical values that would be seen for the product across Abbott ARCHITECT c8000® clinical chemistry systems with the associated reagent test systems. Value assignment ranges were established at the pre-determined criteria of 20%. The values provided in the instructions for use were derived from replicate analyses and are specific for a particular lot of product. Tests were performed by the control manufacturer and/or by independent laboratories, for various methods and instrument systems. Laboratory means may vary from the values listed during the life of the control. Values are provided only as guidelines, each laboratory should establish its own statistical limits.

8.2 Stability Testing Summary

Stability studies have been performed to determine the open vial stability and shelf-life for this control. For open vial stability, Technopath utilized internal procedures and protocols methods.

Product claims are as follows:

Open Vial Stability:

- 14 days at 2 to 8°C

A combination of accelerated and preliminary real-time testing was carried out utilizing procedures and protocols in order to support a shelf-life storage claim of -20° to -80°C for 30 months. The accelerated testing utilized three lots of controls and the real-time testing utilized one lot of controls. All data was generated using the Abbott ARCHITECT c8000 Chemistry system with the associated reagent test systems. The Drift Limit was determined to be 10%. These results concluded that the Multichem P control is predicted to be stable for in excess of 30 months when stored at -20°C to -80°C. The real-time testing is on-going.

Note: ARCHITECT and c8000 are trademarks of Abbott Laboratories.

8.3 Traceability Summary

The analytes contained within the Multichem P control were obtained from commercially available sources or endogenous components to the base serum matrix. Techno-path does not claim traceability to higher order reference materials or methods.

9.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the Multichem P control is as safe, as effective, and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TECHNO-PATH MANUFACTURING LTD.
C/O MS. STEPHANIE G. GARTH
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September 25, 2013

Re: K131992
Trade/Device Name: Multichem P
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I
Product Code: JJY
Dated: August 20, 2013
Received: August 23, 2013

Dear Ms. Garth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131992

Device Name
Multichem P

Indications for Use *(Describe)*

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Ceruloplasmin
Complement C3
Complement C4
C-Reactive Protein
Haptoglobin
Immunoglobulin A
Immunoglobulin G
Immunoglobulin M
Prealbumin
Rheumatoid Factor (RF)
Transferrin

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S